

## REMARKS

Claims 1-18 were pending.

Claim 13 is cancelled.

Claims 1, 2, 14, 16 and 18 are amended.

Claims 1-12 and 14-18 are pending.

### **Amended Claims**

Claim 1 is amended to remove the terms "substantially no removal" and required that cellular material and/or components of a fermentation broth be present during the polymerization.

Claim 1 is amended to change the term "obtainable" to "obtained".

Claim 2 antecedent basis is corrected by inserting the term "broth".

Claim 18 is amended to change the term "obtainable" to "obtained".

Applicants have reformatted claim 14 to comply with the Examiner's request to separate the step by line breaks.

Applicants have deleted the preferable ranges in claim 16.

No new matter has been added.

### **Listing of Commonly Owned Applications and Patents**

Applicants enclose form PTO/SB0206 which list three applications filed by at least one common inventor listed on the present application. Furthermore, each of the applications claim the same priority date of December 2, 2003.

10/580,445 claims a process for producing a monomer.

10/580,446 claims a method of producing an amide from the corresponding nitrile.

10/580,448 claims a microorganism, method for culturing and a process of preparing an amide from a nitrile.

As the present application claims a process for the preparation of a polymer, there is no overlap between the present application's claims and any of the cited co-pending application claims.

Thus none of the listed co-pending application contain at least one patentable indistinct claim.

### **35 USC 112, first paragraph**

Please find enclosed herewith the deposit receipt and the viability statement for the strain NCIMB 41164 which describe all necessary items.

Thus the material has been accepted for deposit under the Budapest treaty on the international Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure and all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

### **35 USC 102(b) Rejection over US 4,343,900**

Example 1 of US 4,343,900 describes at first a process of producing immobilized or "fixed" cells on a polyacrylamide gel. How the monomer (acrylamide) is obtained, is not defined. Hence, the polymerisation in the presence of resting cells cannot be regarded as an anticipating reference.

The gel including the fixed cells is pulverized and fully washed with a 0.1% aqueous solution of acrylic acid, which had been neutralized with sodium carbonate to pH 8. Because of this washing step there are no components of the fermentation broth or cellular material in the effluent of the acrylamide solution after conversion from the acrylonitrile. In col. 4, line 8 this is supported, because the term "gel-entrapped" makes clear that there is no biomaterial other than the fixed cells. For the sake of clarity, applicants mention that the fixed cells used in the glass columns of example 1 remain there (in analogy to column chromatography). Finally, nothing is mentioned in US 4,343,900 that there is any biomaterial present during polymerisation of the obtained acrylamide. Hence, polymerizing of the acrylamide takes place without any such biomaterial and the process by Watanabe is different to the claimed process.

**35 USC 102(b)/103(a) Rejection over WO 97/06248 A1, alternatively over WO 97/06248 A1 in view of US 5,352,828**

In point 24) of the office action examiner states:

"Armitage teaches a process for preparing a polymer (a homopolymer or copolymer of methacrylamide) of an ethylenically unsaturated monomer wherein the monomer is obtained from a fermentation process, and forming the polymer by polymerizing the ethylenically unsaturated monomer."

" Armitage teaches that the monomer may be prepared by providing a substrate, such as methacrylonitrile, that can be converted into the monomer, contacting the substrate with a biocatalyst, such as a microorganism or cellular material, and converting the substrate into the monomer"

Examiner refers to p. 13, lines 23-31 and p. 15, lines 14-35 respectively for the basis of his analysis.

The applicants however, respectfully disagree that the above passages support the examiners' analysis.

Firstly, WO 97/06248 A1 relates to processes for the production of novel amidase or nitrilase enzymes. WO 97/06248 relates to a method of converting unsaturated amides to their corresponding unsaturated acids or acid salts using an amidase enzyme. The amidase is effective for converting (meth)acrylamides to ammonium (meth)acrylate, for instance during or after the polymerisation of an acrylamide.

The applicants point out that acrylamide cannot be obtained from acrylonitrile with the help of an amidase or a nitrilase. The method disclosed in WO 97/06248 may be used for the purification of polymers which have been formed from acrylamide monomers, with or without comonomers. So, the amidase is used to convert (meth)acrylamide monomer to ammonium acrylate monomer, or the amidase is used to reduce residual free (meth)acrylamide in poly(meth)acrylate.

The relevant passage on page 13 says: ...we make a polymer of (meth)acrylamide by a process which comprises providing an aqueous polymerisable mixture containing (meth)acrylamide in a reaction vessel, exothermically polymerising the polymerizable mixture and recovering the resultant

polymer from the reaction vessel, and in this process the residual (meth)acrylamide content of the polymer is reduced by incorporating in the polymerisable mixture the amidase ...

The amidase enzyme may be introduced into the reaction mixture (containing acrylamide monomer or impure polyacrylamide) in any suitable form ... pure form ... semi-pure form, for instance as liquid culture or a bacterial cell fraction such as intact cells or crushed cells ... (page 14).

WO 97/06248 also discloses combining the amidase enzyme and/or microorganism in the polymerisable mixture containing acrylamide and then polymerising this mixture to form the polymer, wherein the residual (meth)acrylamide content is reduced.

Applicants bring to the examiner's attention, that the amidase biocatalyst does not form the monomer to be polymerised, but is added in a separate step (see the description of the prior art in the present application on page 5, lines 16-30).

The present claims require that the polymer is polymerized wherein there is substantially no removal of the cellular material and /or components of the fermentation broth from the ethylenically unsaturated monomer. WO 97/06248 never discloses or suggests the formation of acrylamide then ... using the same broth to run the polymerization reaction.

Secondly, WO 97/06248 A1 describes a method of converting a nitrile to its corresponding acid or acid salt using the novel nitrilase enzyme. This nitrilase enzyme is useful for the conversion of (meth)acrylonitrile into ammonium (meth)acrylate. **This nitrilase enzyme is not useful for conversion of (meth) acrylonitrile into acrylamide.**

Hence, WO 97/06248 A1 differs from the present invention in that the cellular material or the components of the fermentation broth comes from the amidase enzyme production (producing the enzyme in a growth medium comprising a carbon source, e.g. acrylamide, see page 3, lines 32-37 and p. 5, line 34). Acrylamide is not produced in this fermentation broth. Therefore the presently claimed process is novel.

Also, no hint is given in WO 97/06248 A1 which would motivate a person skilled in the art to modify the process of WO 97/06248 A1 in order to arrive at the presently claimed invention.

**In regard to the rejection over WO 97/06248 A1 in view of US 5,352,828:**

The examiner is of the opinion that Seki teaches that, under most conditions, polymerization of a solution of acrylamide will occur, if they are not stabilized (US 5,352,828; col. 2, lines 13-19). Further stated by the examiner, polymerization would inherently occur in the process of WO 97/06248 A1.

This is however, beside the point WO 97/06248 is an inappropriate reference as it does not suggest or disclose the preparation of a monomer via biocatalysis or a fermentation process and then taking that same broth with no removal of the cellular material and polymerizing. US 5,352,828 does not make up for this deficiency.

In fact, US 5,352,828 discloses, that the aqueous acrylamide solution was produced by a microbiological method. Also, a possible acrylamide polymerization of a stabilized solution is mentioned (col. 3, lines 31-35). However, especially example 2 (col. 4, lines 42-48) describes that after completion of the reaction (conversion of the acrylonitrile into the acrylamide) the biological catalyst was removed.

Therefore, with regard to US 5,352,828 alone or combined with another document, especially WO 97/06248 A1, no hint is given for modifying the process which would result in the claimed process.

**35 USC 103 Rejection over US 4,348,900 in view of WO 97/06248 A1**

Both documents relate to the polymerisation of an ethylenically unsaturated monomer.

As mentioned under 3) the process of polymerisation of acrylamide takes place either without any biomaterials, or with acrylamide whose manufacture is unknown (US 4,348,900).

As discussed above, WO 97/06248 A1 relates to novel amidase enzymes which are effective for converting (meth)acrylamides to ammonium (meth)acrylate, for instance during or after the polymerisation of an acrylamide.

The combination of the two documents does not result in the claimed invention, because the second feature "wherein the monomer contains cellular material and/or components of a fermentation broth" is missing in both processes.

As a conclusion, claim 1, its dependent claims as well as claim 18 are novel and inventive in view of the cited documents.

Reconsideration and withdrawal of the rejection of claims 1-12 and 14-18 is respectfully solicited in light of the remarks and amendments *supra*.

Since there are no other grounds of objection or rejection, passage of this application to issue with claims 1-12 and 14-18 is earnestly solicited.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the examiner contact the undersigned representative.

Respectfully submitted,



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Enclosures: Listing of commonly owned applications and patents and deposit receipt and the viability statement for the strain NCIMB 41164.